K061879

510k Summary

DEC 19 2006

Purpose of Application:

New 510(k) for instrument – instrument performance was established with previously 510(k) cleared assays.

Establish CLIA registration for submitted assays.

Submitter Information:

HemoDiagnostica IVD Systems

Contact Name:	Bruno Borganti
Company Name and Address:	HemoDiagnostica, LLC 345 Freshfields Drive Johns Island SC, 29455
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Date of Submission:

June 29th, 2006

Name of Product:

SDI CA480 Clinical Chemistry System
Saturno 300 Clinical Chemistry System

SDI CA480 Clinical Chemistry System Device Classification:

Device Classification:	II
Product Codes:	JJE and subsequent CEM, CGZ, JGS, CDQ, CFR
Regulation Sections	21 CFR § 862.2160 and subsequent § 862.1600, § 862.1170, § 862.1665, § 862.1770, § 862.1345

Indications for Use:

The SDI CA480 Clinical Chemistry System includes a discrete, random access, microprocessor controlled clinical chemistry analyzer and dedicated reagents intended for *in vitro* diagnostic quantitative measurement of Glucose, Blood Urea Nitrogen (BUN), Sodium, Potassium and Chloride in serum. Other various chemistry assays are adaptable to the analyzer.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. BUN measurements are use in the diagnosis and treatment of certain renal and metabolic diseases. Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance. Potassium measurements monitor electrolyte balance and are used in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

Predicate Device:

Ciba Corning Model 550 Express Clinical Chemistry Analyzer
510(k): K872302

Ciba Corning Model 664/Fast 4 System
510(k): K871028

The following table describes the predicate devices, classifications, corresponding regulations, and product codes associated with this submission.

New Product	Predicate Device	510(K)	Device Class	Product Code	Regulation
SDI CA480 Clinical Chemistry System	Ciba Corning Model 550 Express	K872302	I	JJE	862.2160
	Ciba Corning Model 664/Fast 4 System	K871028	II	CEM	862.1600
	Ciba Corning Model 664/Fast 4 System	K871028	II	CGZ	862.1170
	Ciba Corning Model 664/Fast 4 System	K871028	II	JGS	862.1665
	UREA NITROGEN (BUN)	K880078	II	CDQ	862.1770
	GLUCOSE HEXOKINASE	K880236	II	CFR	862.1345

Device Description:

The SDI CA480 is a discrete, random access, microprocessor controlled photometric analyzer with the capability to perform 300 clinical chemistry tests per hour with an additional 180 ISE tests per hour for a total throughput of 480 tests per hour.

The analyzer is comprised of three main components: sample system, reagent system, and measurement system. The analyzer utilizes hardware controlled robotics for pipetting, transport, dispensing and stirring of reagents and samples. The measurement system features a halogen lamp, filter wheel and photodiode for optical detection and reusable quartz reaction cuvettes which are automatically washed and dried between samples. The integrated ISE module allows for Na/K/Cl electrolyte tests.

Summary of Substantial Equivalence:

The SDI CA480 Clinical Chemistry System is substantially equivalent to the Ciba Corning Model 550 Express Clinical Chemistry Analyzer and the Model 664/FAST 4 System in design, intended use, and technology.

Method Comparison Data:

To demonstrate substantial equivalence between the SDI CA480 and the predicate devices Model 550 Express and Model 664, previously 510(k) cleared assays were tested on each appropriate instrument. A comparison analysis was performed between the SDI CA480 and the Model 550 Express and Model 664 for 60 real patient samples. The results are summarized below.

Assay	Sample Type	Slope	Intercept	Correlation Coefficient
ISE Sodium Electrode	Serum / Plasma	.998	-1.26	.9905
ISE Potassium Electrode	Serum / Plasma	.977	0.06	.9946
ISE Chloride Electrode	Serum / Plasma	1.02	-2.34	.9761
Urea Nitrogen (BUN)	Serum / Plasma	.933	0.94	.9988
Glucose HK	Serum / Plasma	.980	1.34	.9998

Conclusion:

The SDI CA480 Clinical Chemistry System and the Ciba Corning Model 550 Express system combined with optional Model 664/Fast 4 ISE system are substantially equivalent in design, intended use, and in performance.

Bruno Borganti

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Bruno Borganti
HemoDiagnostica, LLC
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DEC 15 2006

Re: k061879
Trade Name: SDI CA480 Clinical Chemistry System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR, CDN, JGS, CEM, CGZ, JJE
Dated: November 22, 2006
Received: November 27, 2006

Dear Mr. Borganti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

K061879

Device Name:

SDI CA480 Clinical Chemistry System

Indications for Use:

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Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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